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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,290	02/07/2001	Michael G. Wyllie	PC10325AAKM	8690

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EXAMINER	
JONES, DWAYNE C	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/778,290	Applicant(s) WYLLIE, MICHAEL G.	
	Examiner Dwayne C Jones	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

1. Claims 1-39 are pending.

2. Claims 1-39 are rejected.

Response to Arguments

3. Applicant's arguments filed June 17, 2002 have been fully considered but they are not persuasive with respect to composition claims 1-28. Applicant's appellant makes the following arguments. First, Heible et al. only teach of a first combination of alpha-adrenoceptor antagonists with 5-alpha-reductase inhibitors and a second combination of an alpha-1-adrenoceptor antagonist with an androgen receptor antagonist. Second, appellant intimates that one skilled in the art would not utilize muscarinic antagonists for treating BPH in view of Heible et al. Third, applicant's attorney argues that Ukimura is directed to the treatment of bladder disorders, in particular detrusor hyperreflexia, which is regarded as non-analoguous art.

4. Foremost, it is pointed out that instant claims 1-28 are composition claims not methods of use. Accordingly, any arguments directed to using the claimed composition for a particular use are found unpersuasive.

5. Responding to appellant's argument that Heible et al. do not teach of the instantly claimed composition of an alpha-adrenergic blocking agent combined with a muscarinic antagonist, the following is noted. Once again, claims 1-28 are composition claims, as such they only require the presence of two components, (1) an alpha-

adrenergic blocking agent and (2) a muscarinic antagonist. In addition, Hieble et al. also teach of pharmaceutical compositions and methods of treating urinary tract ailments, which contain both alpha-adrenoceptor antagonists, (see pages 285s – 286s) and muscarinic cholinergic receptor antagonists, (see pages 286s –288s). Moreover, Hieble et al. is directed to the treatment of diseases, which affect the lower urinary tract, benign prostate hypertrophy and urinary incontinence. Hieble et al. also teach that a form of incontinence can also be induced by urethral obstruction, and may be therefore also be seen in patients with benign prostatic hypertrophy, (see page 285s). Accordingly, the prior art reference of Hieble et al. do provide motivation to use pharmaceutical compositions, which contain both alpha-adrenoceptor antagonists and muscarinic cholinergic receptor antagonists, for treating urinary tract ailments relating to benign prostatic hyperplasia.

6. Third, applicant's attorney argues that Ukimura is directed to the treatment of bladder disorders, in particular detrusor hyperreflexia. However, instant claims 1-28 are composition claims, as such they only require the presence of two components, (1) an alpha-adrenergic blocking agent and (2) a muscarinic antagonist. The prior art reference of Ukimura also discloses of the administration of various types of alpha-adrenergic blocking agents, such as prazosin, and muscarinic antagonists, namely oxybutynin, to treat disorders of the bladder, (see abstract). For these reasons, the instant invention is anticipated by the prior art of Ukimura et al.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 1, 11, 21 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the alpha-adrenoceptor antagonist of 4-amino-6,7-dimethoxy-2-(5-methanesulfonamido-1,2, 3,4-tetrahydroisoquinol-2-yl)-5-(2-pyridyl)quinazoline, doxazosin, tetrazosin abanoquil, prazosin and indoramin and the muscarinic antagonists of darifenacin, tolterodine, oxybutynin, does not reasonably provide enablement for other types of alpha adrenoceptor antagonists and muscarinic antagonists. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. All questions of enablement are evaluated against the claimed subject matter. The question asked by one skilled in the art is whether everything within the scope of the claim is enabled. The instant claims cover all compounds having the pharmaceutical property of being known descriptively as both alpha-adrenoceptor antagonists and muscarinic antagonists. Accordingly, the instant specification only provides guidance and support for 4-amino-6,7-dimethoxy-2-(5-methanesulfonamido-1,2, 3,4-tetrahydroisoquinol-2-yl)-5-(2-pyridyl)quinazoline, doxazosin, tetrazosin abanoquil, prazosin and indoramin; and darifenacin, tolterodine, oxybutynin as embraced by the alpha-adrenoceptor antagonist; the muscarinic antagonists terms, respectively. The Federal Circuit has repeatedly held that "the

specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'." *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). One does not look to the claims but to the specification to find out how to practice the invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1558, 220 USPQ 303, 316-7 (Fed. Cir. 1983); In re Johnson, 558 F.2d 1008, 1017, 194 USPQ 187, 195 (CCPA 1977). Due to the unpredictability in the art, the state of the art and the lack of working examples for compounds other than those recited above, one skilled in the art is subjected to an undue experimentation in order to determine the other compounds which are supported by the pharmaceutical property of being known as alpha-adrenoceptor antagonists and muscarinic antagonists.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-28 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hieble et al. Hieble et al. also teach of pharmaceutical compositions and methods of treating urinary tract ailments, which contain both alpha-adrenoceptor antagonists, (see

pages 285s – 286s) and muscarinic cholinergic receptor antagonists, (see pages 286s – 288s).

10. Claims 1-28 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ukimura. The prior art reference of Ukimura also discloses of the administration of various types of alpha-adrenergic blocking agents, such as prazosin, and muscarinic antagonists, namely oxybutynin, to treat disorders of the bladder, (see abstract).

Claim Rejections - 35 USC § 103.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heible et al. Heible et al. teach that of treating benign prostatic hypertrophy and urinary incontinence with various types of pharmaceuticals, namely alpha-adrenoceptor antagonists, (see pages 277s-283s and 284s-286s) and muscarinic cholinergic receptor

antagonists, (see pages 287s-288s). In fact, Hieble et al. also teach of pharmaceutical compositions and methods of treating urinary tract ailments, which contain both alpha-adrenoceptor antagonists, (see pages 285s – 286s) and muscarinic cholinergic receptor antagonists, (see pages 286s –288s). Hieble et al. also teach that a form of incontinence can also be induced by urethral obstruction, and may be therefore also be seen in patients with benign prostatic hypertrophy, (see page 285s). Accordingly, the prior art reference of Hieble et al. do provide motivation to use pharmaceutical compositions, which contain both alpha-adrenoceptor antagonists and muscarinic cholinergic receptor antagonists, for treating urinary tract ailments relating to benign prostatic hyperplasia.

13. Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ukimura in view of Heible et al. Ukimura teaches of the administration of various types of alpha-adrenergic blocking agents, such as prazosin, and muscarinic antagonists, namely oxybutynin, to treat disorders of the bladder, (see abstract). In addition, Ukimura disclose that the studied pharmaceuticals have the ability to suppress spontaneous bladder contraction. This reference clearly provides motivation to utilize these drugs in other mammals, including humans.

14. Hieble et al. is directed to the treatment of diseases, which affect the lower urinary tract, benign prostate hypertrophy and urinary incontinence. Hieble et al. also teach that a form of incontinence can also be induced by urethral obstruction, and may be therefore also be seen in patients with benign prostatic hypertrophy, (see page 285s). Accordingly, the prior art reference of Hieble et al. do provide motivation to use

pharmaceutical compositions, which contain both alpha-adrenoceptor antagonists and muscarinic cholinergic receptor antagonists, for treating urinary tract ailments relating to benign prostatic hyperplasia. One having ordinary skill in the art at the time of the invention would have been motivated to use the compositions of Ukimura for treating lower urinary tract symptoms which are associated with benign hyperplasia, especially when Hieble et al. teach of pharmaceutical compositions and methods of treating urinary tract ailments that can also been seen in patients with benign prostatic hypertrophy.

15. The rejection of claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cilluffo et al. is withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

DWAYNE C. JONES
PRIMARY EXAMINER
Tech. Ctr. 1614
September 9, 2002